

REMARKS

Non-Statutory Double Patenting

The Examiner rejected Claims 1-4 under judicially created doctrine obviousness-type double patenting as being unpatentable over Claims 1-3, 5 and 8 of U.S. Patent No. 6,974,795 ('795). Since the '795 patent is commonly owned with this application, a terminal disclaimer is attached to this amendment to overcome this nonstatutory double patenting rejection.

Rejection under 35 U.S.C § 112, first paragraph

The Examiner has also rejected Claims 1-4 and 7 under 35 U.S.C § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the last office action response (filed December 22, 2006) Applicants amended Claim 1 to specifically point out that the surface-modified hemoglobin is polyethylene glycol surface modified hemoglobin that has an oxygen affinity less than that of strama-free hemoglobin.

However, there was a typo in amended Claim 1, wherein "strama" should have been "stroma." Applicants have corrected this typo in the current claim amendments.

The Examiner stated that the claimed invention is directed to a blood substitute composition comprising a PEG surface-modified hemoglobin, however, the claims are described by functional means and no structural limitation is present in the claims. The rejection is traversed and reconsideration is respectfully requested on the basis of the discussion that follows.

Applicants have amended Claim 1 to read: "A blood substitute composition comprising polyethylene glycol surface-modified hemoglobin having an oxygen affinity less than that of stroma-free hemoglobin, and an aqueous diluent, wherein the aqueous diluent is at least 40% plasma."

There are a variety of different hemoglobin modifications discussed in the instant specification. For example, the paragraph 0047 of the specification recites that "the oxygen-carrying component is modified hemoglobin. A preferred modification to hemoglobin is 'surface-modification,' i.e. covalent attachment of chemical groups to the exposed amino acid side chains on

the hemoglobin molecule. Most commonly, the chemical group attached to the hemoglobin is polyethylene glycol.”

The other claimed characteristic of the surface-modified hemoglobin is that it has a high oxygen affinity. In fact, it has an oxygen affinity that is less than that of stroma-free hemoglobin. Support for this characteristic is found in paragraph 0044, which recites that “HBOC with oxygen affinity less than that of SFH is desired,” wherein HBOC stands for hemoglobin-based oxygen carriers and SFH stands for stroma-free hemoglobin.

Thus, it will be readily apparent to those skilled in the art that the claimed blood substitute composition that contains polyethylene glycol covalently attached to the hemoglobin molecule, and has an oxygen affinity less than that of stroma-free hemoglobin. Applicants believe that the subject matter claimed in amended claim 1 and its claims 2-4 and 7 which depend thereon are now adequately described and fully supported by the original disclosure as filed.

SUMMARY

It is believed that the foregoing amendment and argument deals with all grounds of objection and rejection, and that the claims remaining in this application are in order for allowance.

Should the Examiner believe that prosecution of this application might be expedited by further discussion of any remaining issue, the Examiner is cordially invited to contact the undersigned representative for the Applicants by phone at (619) 230-7478 or by email at llloyd@gordonrees.com.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1990 and please credit any excess fees to such deposit account.

Respectfully submitted,

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